NOV 1 9 2002

K023516

AMERICAN MEDICAL SYSTEMS

510(k) SUMMARY

Submitter's Name:	American Medical Systems, Inc.
Address:	10700 Bren Road West Minnetonka, MN 55343
Tel:	952-933-4666
Fax:	952-930-6496
Contact Person:	David Worrell
Date of Summary Preparation:	October 15th, 2002
Device Common Name:	Surgical Mesh, Sling, Urethral Sling
Device Trade Name:	MONARC™ Sling System
Device Classification Name:	Surgical Mesh, polymeric
Predicate Device:	SPARC™ Sling System – K011251, K013355, K020663, K021263

Device Description

The MONARC Sling System is a sterile, single use procedure kit consisting of two stainless steel, 22cm spiral needle passers (also called insertion tools) and one AMS polypropylene sling mesh with attached dilating connectors. The dilating connectors attach to the keyed ends of the MONARC needle passers during the procedure to facilitate sling placement. A fixed absorbable PGA tensioning suture runs through the middle of the sling mesh. Two plastic sheaths overlap in the center of the sling mesh and protect it during placement.

Indications for Use

The MONARC Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Comparison to Predicate Device

The fundamental scientific technology of the MONARC device is unchanged from the predicate device. The primary change to the device is the shape of the needle. The needle will have a spiral shape instead of a curved shape. The sling mesh and absorbable suture remain the same. The devices that were the subject of K020663 and K021263 will continue to be marketed.

Supporting Information

A risk analysis for the MONARC device and the verification and validation activity reported in this 510(k) application substantiate equivalence to the predicate and did not raise any new questions of safety or effectiveness.

Conclusion

The MONARC device is substantially equivalent to the predicate with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

American Medical Systems, Inc.
David Worrell
Sr. Regulatory Affairs Specialist
10700 Bren Road, West
Minnetonka, Minnesota 55343

Re: K023516
Trade/Device Name: Monarc™ Sling System
Regulation Number: 878.3300
Regulation Name: Surgical mesh, polymeric
Regulatory Class: Class II
Product Code: FTL
Dated: October 17, 2002
Received: October 21, 2002

Dear Mr. Worrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number: K023516

Device Name: MONARC™ Sling System

Indications for Use: The MONARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

510(k) Number K023516

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023516